UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

IN RE FLINT WATER LITIGATION	Case No. 5:16-cv-10444-JEL-MKM Hon. Judith E. Levy
This Document Relates To: *Gaddy et al. v. Flint et al.* *Meeks et al. v. Flint et al.*	 Case No. 5:17-cv-11166-JEL-MKM Case No. 5:17-cv-11165-JEL-MKM

DEFENDANTS VEOLIA NORTH AMERICA, LLC, VEOLIA NORTH AMERICA, INC., AND VEOLIA WATER NORTH AMERICA OPERATING SERVICES, LLC'S MOTION TO EXCLUDE THE TESTIMONY AND REPORT OF AARON SPECHT, PH.D.

Pursuant to Federal Rules of Evidence 702, 402, and 403, Defendants Veolia North America, LLC, Veolia North America, Inc., and Veolia Water North America Operating Services, LLC (VNA) move to exclude the testimony and report of Aaron Specht, Ph.D. Dr. Specht's opinions are not based on a reliable methodology; they would not be helpful to a jury's evaluation of whether Plaintiffs experienced significant lead exposures as a result of the Flint water crisis in 2014-2015 generally or VNA's alleged acts or omissions in February to March 2015 in particular; and they would be substantially more prejudicial than probative.

As Local Rule 7.1(a) requires, VNA conferred with Plaintiffs' counsel concerning this motion. After VNA explained the nature and legal basis for the motion, Plaintiffs' counsel said that they would oppose it.

Respectfully submitted,

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Dated: May 11, 2021

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DEFENDANTS VEOLIA NORTH AMERICA, LLC, VEOLIA NORTH AMERICA, INC., AND VEOLIA WATER NORTH AMERICA OPERATING SERVICES, LLC'S BRIEF IN SUPPORT OF THEIR MOTION TO EXCLUDE THE TESTIMONY AND REPORT OF AARON SPECHT, PH.D.

STATEMENT OF THE ISSUE PRESENTED

1. Should the Court exclude the testimony and report of Dr. Aaron Specht under Federal Rules of Evidence 702, 402, and 403 because they are not based on a reliable methodology or on sufficient facts or data, would not be helpful to the trier of fact, and would be substantially more prejudicial than probative?

VNA answers: "Yes."

Plaintiffs answer: "No."

CONTROLLING OR MOST APPROPRIATE AUTHORITIES

City of Pomona v. SQM N. Am. Corp., 750 F.3d 1036 (9th Cir. 2014)

Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993)

Dombrowski v Gould Elecs., Inc, 31 F. Supp. 2d 436 (M.D. Pa. 1998)

Nelson v. Tenn. Gas Pipeline Co., 243 F.3d 244 (6th Cir. 2001)

United States v. Semrau, 693 F.3d 510 (6th Cir. 2012)

Fed. R. Evid. 402

Fed. R. Evid. 403

Fed. R. Evid. 702

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INTRODUCTION

Dr. Aaron Specht is a medical physicist who offers opinions about measurements of lead in Plaintiffs' bones. These measurements were taken using portable x-ray fluorescence (pXRF) devices. These devices were manufactured for industrial use but modified by Dr. Specht for use in measuring bone lead in humans. Based on the measurements, Dr. Specht opines that each of the 13 bellwether plaintiffs, including the four Plaintiffs who have been selected for the first bellwether trial—E.S., A.T., R.V., and D.W. (Plaintiffs[1])—experienced a [redacted] during his or her development. The bone lead measurements and Dr. Specht's opinions about them should be excluded because they are unreliable and unhelpful.

First, Dr. Specht's pXRF technology is not a reliable way to measure bone lead levels in children. Dr. Specht himself characterized a different technology—K-shell x-ray fluorescence (KXRF)—as the "gold standard" for measuring bone lead levels. Yet Plaintiffs' bone lead was measured using portable pXRF devices instead. Dr. Specht and his colleagues have been unable to show that these devices accurately measure bone lead in children. In fact, in peer-reviewed research, Dr. Specht and his colleagues have found that pXRF devices do *not* produce accurate bone lead

[1] To be precise, the guardians of E.S., A.T., R.V., and D.W. are the actual plaintiffs. But for the sake of simplicity, VNA will refer to E.S., A.T., R.V., and D.W. as Plaintiffs.

measurements in children because children have thicker soft tissue overlaying their bones and different bone composition than adults.

Second, Dr. Specht has no reliable basis for concluding that Plaintiffs' bone lead levels reflect [redacted]. All children have lead in their bones from a variety of sources, and Dr. Specht concedes that there are no accepted benchmarks for designating bone lead as [redacted] Dr. Specht attempts to support his opinions by comparing the Flint bone lead readings to measurements taken in studies in China and Canada. But those studies do not support Dr. Specht's conclusions, because Plaintiffs' bone lead levels [redacted], and because the results from Canada used KXRF technology, not pXRF technology. Further, Dr. Specht did not use any control group, and without a control group, he could not reliably conclude that Plaintiffs [redacted]. Notably, Dr. Howard Hu, who has studied bone lead for decades and has been retained by the class plaintiffs, testified that he did not perform any bone lead testing in Flint because he did not see its utility and because there is no standard against which to compare the results.

Finally, the bone lead data and Dr. Specht's opinions should be excluded because Dr. Specht cannot show that any incremental lead exposure occurred during the Flint water crisis, much less because of anything that VNA did or did not do. Dr. Specht concedes that an individual's bone lead level is the result of cumulative

exposures and that he cannot identify when or how a child was exposed to lead. And Plaintiffs' other experts acknowledge that Plaintiffs were exposed to lead from sources other than the Flint water crisis. Dr. Specht's bone lead measurements therefore cannot show lead exposure caused by the Flint water crisis in 2014-2015, much less lead exposure specifically due to VNA's allegedly negligent acts or omissions in February-March 2015. Thus, the bone lead readings cannot assist the jury to resolve any issue in the case and, if admitted, would be substantially more prejudicial than probative and would confuse and mislead the jury.

For all of those reasons, the bone lead measurements and Dr. Specht's opinions about them should be excluded.

Relatedly, Dr. Specht opines that blood lead levels have limited value in assessing exposure because the half-life of lead in blood is supposedly less than one week. But Dr. Specht's opinion that lead in blood has a half-life of less than one week is not reliable. He bases his opinion on his own, limited research on the issue, and he embellishes his own findings. He also ignores the broader scientific literature, which shows that the half-life of lead in children's blood actually is quite long—typically a year or more. Accordingly, Dr. Specht's opinion about the half-life of lead in blood is unreliable and should be excluded.

BACKGROUND

Dr. Specht received a B.S. in physics in 2012 and a Ph.D. in medical physics in 2016, both from Purdue University. Ex. 2, Specht CV. He is a research associate at the Harvard T.H. Chan School of Public Health. *Id.* His research focuses on "[n]ovel applications of nuclear instrumentation as exposure assessment in health studies" and the "[d]evelopment of novel nuclear technologies for occupational and environmental exposure assessment." *Id.* For this case, Plaintiffs had bone lead scans performed under Dr. Specht's direction. Dr. Specht supplied pXRF devices, Plaintiffs' counsel hired nurses, and the nurses performed the scans on Plaintiffs in conference rooms in counsel's law offices. Ex. 3, Specht Dep. 12:20-14:10, 29:18-32:3, 78:23-85:24 (Dep.). Dr. Specht then provided opinions about the bone lead scan results.

A. KXRF vs. pXRF Technology

Dr. Specht opines that x-ray fluorescence (XRF) is the "most successful and least invasive method" for measuring bone lead. Ex. 4, Specht Report 4 (Report). He testified that one form of XRF—KXRF—has been the "gold standard" for measuring bone lead since the 1990s. Dep. 224:3-225:1. KXRF devices use a high-energy K-shell x-ray that measures lead content throughout an entire bone. *Id.* at 224:15-225:12, 297:16-19. To ensure an accurate reading, a KXRF measurement

takes 30 minutes to complete. *Id.* at 226:3-7. A KXRF device is available at Purdue University, a few hours from Flint. *Id.* at 293:20-294:1.[2]

But Dr. Specht did not use what he characterizes as the "gold standard" KXRF to measure Plaintiffs' bone lead. Instead, under Dr. Specht's supervision, nurses hired by Plaintiffs' counsel measured Plaintiffs' bone lead levels using handheld pXRF devices. Dr. Specht and his colleagues purchased pXRF devices that are normally used for mining exploration, soil analysis, and consumer goods testing, and then modified both the devices and their software to use them to measure lead in bones. *See* Dep. 45:20-46:12, 213:3-214:22, 495:15-498:24; Ex. 5, Thermo Fisher Scientific Niton Analyzers, *XL3 Analyzer User's Guide Version 7.0.1* 1-4 (Nov. 2010) (Thermo Fisher, *XL3 User Guide*). Dr. Specht's modified pXRF devices have not been approved by the Food and Drug Administration as safe and effective for use on human subjects, let alone children. Indeed, the instruction manual for the

[2] Although KXRF has been used to measure bone lead since the 1990s, primarily for research purposes, KXRF also has limitations. VNA is not aware of any reported case in which a court found that KXRF measurements were reliable for proving causation or injury. In fact, leading toxic-tort practice guides suggest otherwise. *See, e.g.*, 2 Toxic Torts Litig. Guide § 19:42 (2020) ("Two XRF technologies have been developed, [KXRF] and [LXRF]. The KXRF technology has been more widely used and is better validated, although it is not a common diagnostic tool."); 1 Toxic Torts Prac. Guide § 3:8 (2020) (explaining that KXRF is a "relatively new marker of cumulative dose that has limitations, *e.g.*, there are factors affecting precision such as movement of the subject's leg out of the field and measurement calibration standards for KXRF instruments have not yet been established").

devices makes clear that they were not intended for use on, and should not be pointed at, human subjects. *See, e.g.*, Ex. 5, Thermo Fisher, *XL3 User Guide* 3-4, 7, 10-11.

Dr. Specht testified that he and his colleagues are the only people in the world using pXRF devices to measure bone lead. Dep. 307:2-20. According to Dr. Specht, "[n]o one else" has the ability to do so because only he has developed the modifications to the pXRF device and software that are necessary for this use. *Id.* at 499:13-21.

Dr. Specht's handheld pXRF device operates differently from KXRF technology. While KXRF devices use high-energy K-shell x-rays to measure lead content throughout an entire bone, the pXRF device uses lower-energy L-shell x-rays that can measure lead content only on the bone surface and a few millimeters into the bone. Dep. 297:10-15.[3] As VNA's expert toxicologist Dr. Brent Finley explains, studies have shown that the accuracy of L-shell x-rays decreases significantly when the thickness of the tissue over the bone increases. Ex. 6, Finley Report 82. Dr. Specht admitted that, as compared to KXRF technology, the pXRF device's measurements are more affected by the thickness of the skin and tissue overlaying a bone. Dep. 143:20-144:18, 156:18-157:24. That is important because Dr. Specht relies on bone lead measurements taken from Plaintiffs' tibias, and

[3] K-shell and L-shell refer to different layers of electron shells orbiting an atom's nucleus and have different energies. *See, e.g.*, Report 4-5.

children typically have thicker soft tissue over their tibias than adults, which materially reduces the accuracy of the measurement. Ex. 6, Finley Report 83.

Dr. Specht's handheld pXRF device also uses shorter, less reliable measurement times. Whereas KXRF devices take 30-minute measurements, the pXRF measurements here were performed in three minutes. Dep. 42:17-43:21, 226:3-7. Dr. Specht has experimented with different measurement times. Before his work in Flint, Dr. Specht had experimented with two-minute readings. *Id.* at 181:3-16, 258:21-259:12. More recently, Dr. Specht has begun experimenting with five-minute readings and has found that longer readings reduce the uncertainty values associated with the measurements. *Id.* at 426:21-430:19. Nonetheless, Dr. Specht did not use five-minute measurements in Flint. *Id.*

The following chart summarizes the key differences between KXRF technology and the handheld pXRF devices used by Dr. Specht:

KXRF	**Handheld pXRF**
Used since the 1990s	Device and software modified by Dr. Specht and his colleagues; used only by them; impossible to replicate the results
Higher-energy K-shell x-ray	Lower-energy L-shell x-ray
Measures lead content of entire bone	Measures lead content of bone surface and a few millimeters into the bone
30-minute measurement	3-minute measurement
Less affected by tissue thickness	More affected by tissue thickness

B. Plaintiffs' Bone Lead Measurements

Dr. Specht did not personally take Plaintiffs' bone lead measurements. Instead, he trained nurses hired by Plaintiffs' counsel to take bone lead measurements of more than 3,000 Flint plaintiffs using two handheld pXRF devices. Dep. 12:20-14:10, 29:18-32:3. That testing began in August 2019, *id.* at 10:20-23, nearly four years after the City of Flint switched back to Detroit water and stopped using the Flint River as its water source, Flint Water Advisory Task Force, *Final Report* 21 (Mar. 2016), *In re Flint Water Litig.*, No. 16-cv-10444 ECF No. 1208-109, PageID.36973.

In his report, Dr. Specht provides the results of the pXRF measurements for 13 bellwether plaintiffs, including E.S., A.T., R.V., and D.W. The reported bone lead levels for the 13 plaintiffs ranged from [redacted] Report 7-20. [redacted] *Id.* The four Plaintiffs who were ultimately selected for trial had bone lead measurements of [redacted] and [redacted] *Id.*

Dr. Specht opines that [redacted] Report 14, 16-17, 19. He concludes that the bone lead levels show [redacted] *Id.* He also takes the view that [redacted]

[redacted] *Id.* He testified in his deposition, however, that he offers no opinions on whether any plaintiff's claimed health problems are (or even could be) the result of lead exposure. Dep. 485:17-486:10. He said that he is "strictly being tasked with performing the bone lead measurements themselves and getting the bone lead results for these four clients, not reviewing their medical records and making an informed decision about causation." *Id.* at 209:5-21.

LEGAL STANDARDS

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the Supreme Court imposed on district courts a "basic gatekeeping obligation" to evaluate proposed expert testimony to ensure that it is both relevant and reliable. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147 (1999). As the proponents of the expert testimony, Plaintiffs bear the burden of establishing its admissibility by a preponderance of evidence. *Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 251 (6th Cir. 2001).

A qualified expert may provide opinion testimony only if it will "help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a). Like all evidence, expert testimony also must be relevant, meaning that it must have a "tendency to make a fact more or less probable." Fed. R. Evid. 401(a), 402. To satisfy Rule 702's requirement that testimony be helpful to the trier of fact, the sponsor of the expert testimony must establish that there is a "fit" between the

proffered expert testimony and "an[] issue in the case." *Daubert*, 509 U.S. at 591. Put another way, "there must be a connection between the scientific research or test result being offered and the disputed factual issues in the case in which the expert will testify." *Pride v. BIC Corp*., 218 F.3d 566, 578 (6th Cir. 2000).

The expert opinion also must be "based on sufficient facts or data," Fed. R. Evid. 702(b), meaning that it "must be of a type reasonably relied upon by experts" in the same field, *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 748 (3d Cir. 1994) (citing Fed. R. Evid. 703). The opinion also must be "the product of reliable principles and methods," which the expert must have "reliably applied . . . to the facts of the case." Fed. R. Evid. 702(c)-(d).

The Supreme Court has identified four non-exclusive factors that bear on whether an expert's methodology "rests on a reliable foundation." *Daubert*, 509 U.S. at 597. Those factors are (1) "whether a theory or technique can be or has been tested"; (2) "whether it has been subjected to peer review and publication"; (3) "whether a technique has a known or potential rate of error and the existence of standards controlling its operation"; and (4) "whether the theory or technique enjoys general acceptance in a relevant scientific community." *Nelson*, 243 F.3d at 251 n.5 (citing *Daubert*, 509 U.S. at 593-94).

Rule 403 permits the exclusion of relevant evidence when "its probative value is substantially outweighed by a danger of" "unfair prejudice, confusing the issues,"

or "misleading the jury." Fed. R. Evid. 403. The Supreme Court has recognized that Rule 403 is especially important when evaluating expert testimony, because "[e]xpert evidence can be both powerful and quite misleading." *Daubert*, 509 U.S. at 595 (internal quotation marks omitted); *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d at 747 (explaining that "Rule 403 gives a judge more power over experts than over lay witnesses"); *see United States v. Norwood*, 16 F. Supp. 3d 848, 865 (E.D. Mich. 2014) (excluding expert's testimony "because of the risk his testimony would confuse or mislead the jury").

ARGUMENT

I. Dr. Specht Did Not Employ A Reliable Methodology For Measuring Bone Lead In Children

Dr. Specht's report and opinions should be excluded because the pXRF devices used to measure Plaintiffs' bone lead have not been shown to accurately measure bone lead levels in children. Dr. Specht has repeatedly attempted to validate his pXRF methodology for use in children but has been unable to do so. All of the reliability factors identified by the Supreme Court—testing, peer review and publication, existence of known rates of error and standards, and general acceptance—confirm that pXRF devices are unreliable when used on children.

A. pXRF Has Been Tested On Children In Peer-Reviewed Research And Has Been Found To Be Unreliable

Two critical factors for evaluating reliability are whether a methodology has been tested and whether it has been subjected to peer review and publication.

Daubert, 509 U.S. at 593. The Supreme Court has explained that "[s]cientific methodology today is based on generating hypotheses and testing them"; that is "what distinguishes science from other fields of human inquiry." *Id.* (internal quotation marks omitted). Moreover, "submission to the scrutiny of the scientific community is a component of 'good science,' in part because it increases the likelihood that substantive flaws in methodology will be detected." *Id.* at 593-94.

Here, testing and peer review have established that Dr. Specht's methodology is not reliable. Dr. Specht has conducted several studies evaluating the reliability of pXRF technology for measuring bone lead, two of which focused on children, and has published the results of his research in peer-reviewed papers. That research shows that pXRF is *not* reliable for measuring bone lead levels in children because children have thicker soft tissue overlaying their bones and different bone composition than adults. And Dr. Specht's results cannot be replicated—which is another red flag showing that his methodology is unreliable.

1. Dr. Specht's Own Research Has Demonstrated That pXRF Testing Does Not Accurately Measure Bone Lead In Children

Dr. Specht's findings in peer-reviewed studies published in 2014, 2016, and 2019 have demonstrated that pXRF is not a reliable method for measuring bone lead in children.

In the 2014 paper, Dr. Specht attempted to validate his pXRF device by measuring lead levels in cadaver bones using both KXRF and pXRF at various tissue thicknesses overlaying bones (1.3, 4.1, and 5.6 mm). *See* Ex. 7, A. Specht et al., *Portable XRF Technology to Quantify Pb in Bone In Vivo*, 2014 J. of Biomarkers, no. 398032 (Specht 2014). The study results showed "excellent agreement of bone [lead] concentrations for cadaver bones at [tissue] thickness of 1.3 and 4.1 mm," but showed that "the agreement deteriorates at 5.6 mm." *Id.* at 7. Dr. Specht explained that, as he expected, higher errors and variations "are associated with larger soft tissue thicknesses." *Id.* at 6. His paper concludes that he was able to "validate[] an advanced [pXRF] system for *in vivo* [lead] measurement and demonstrate[] the validity of using such a system to accurately quantify [lead] in bone with soft tissue thickness *up to 4-5 mm*." *Id.* at 7-8 (emphasis added).

The problem here is that children generally have soft tissue thicknesses above 4-5 mm. As VNA's toxicology expert Dr. Brent Finley explains, children generally have thicker tissue overlaying their tibias relative to adults. Ex. 6, Finley Report 83. For example, in a recent study of 100 children, the mean tissue thickness over the tibia was reported to be 6.8 mm, with a maximum of 13.2 mm. *Id.* (citing Ex. 8, A. Al-Shibli et al., *Determination of the Pretibial Soft Tissue Thickness in Children: Are Intraosseous Infusion Needles Long Enough?*, 36 Pediatric Emergency Care 39 (2020)). At his deposition, Dr. Specht admitted that he did not know Plaintiffs'

tissue thickness. Dep. 148:8-14. He said that he could attempt to calculate the thickness of each Plaintiff's soft tissue based on his pXRF data, but he has not done so. *Id.* at 148:15-149:18. That is a significant omission, because the soft tissue covering a typical child's tibia is thick enough to make the pXRF device's measurements inaccurate.

In the 2016 paper, Dr. Specht attempted to validate pXRF for use on children by comparing pXRF and KXRF measurements taken from lead-poisoned children and from a control group in China. *See* Ex. 9, A. Specht et al., *XRF-Measured Bone Lead (Pb) as a Biomarker for Pb Exposure and Toxicity Among Children Diagnosed with Pb Poisoning*, 21 Biomarkers 347 (2016) (Specht 2016). He conducted the study with the express purpose of showing that pXRF could accurately measure bone lead in children. *See id.* at 2 (stating that the study sought "to validate the use of portable XRF for bone [lead] measurement among children").

Dr. Specht instead found that his pXRF measurements were not accurate. He explained that "[t]he portable XRF in comparison to the KXRF results gave a correlation less than what we would expect based on previous observations in adults and lab samples." Ex. 9, Specht 2016 at 6. He attributed the poor performance of pXRF to children having thicker soft tissue covering their bones and different bone composition than adults. *Id.* at 6-7. With respect to bone composition, he explained that children on average have more fatty tissue in their bones and have a lower bone

density, which affects the calibration of the pXRF device. *Id.* at 6. He concluded that "[s]ince KXRF is a gold standard for *in vivo* bone [lead] measurement, the correlation between KXRF and portable XRF demonstrates the limited ability of the portable XRF with current calibration methods to quantify bone [lead] in children." *Id.* He also cautioned that "further investigation on the effect of bone composition and an improved calibration method would be necessary to obtain more accurate results" and would "need to be addressed before [pXRF is] used further in pediatric populations." *Id.* at 7. In other words, Dr. Specht's 2016 study concluded that pXRF did not accurately measure bone lead in children.

Dr. Specht acknowledged the same limitations of pXRF technology compared to KXRF in his Ph.D. thesis, which he completed in 2016. *See* Ex. 10, A. Specht, *X-ray Fluorescence for Quantification of Lead and Strontium In Vivo* (2016). Dr. Specht wrote that KXRF technology has "advantages [over] current portable XRF technology because it would not have the significant issues with skin thickness degrading the measurement." *Id.* at 110. He said that "[b]y using the high-energy of KXRF we can avoid the substantial limitations of soft tissue thickness that are prevalent in the portable XRF." *Id.* at 114.

In a paper published in 2019—at the same time he was overseeing the use of pXRF devices on Plaintiffs in Flint—Dr. Specht again attempted to validate pXRF for use on children through a follow-up study in China. *See* Ex. 11, A. Specht et al.,

Childhood Lead Biokinetics and Associations with Age Among a Group of Lead Poisoned Children in China, 29 J. Expo. Sci. Env't Epidemiol. 416 (2019) (Specht 2019). The study's goal was to "evaluate[] the use of [pXRF] in comparison to [KXRF] as a measure of bone [lead]." *Id.* at 2.

But once again, Dr. Specht could not validate the use of pXRF to measure bone lead in children. The study continued to show a poor correlation between pXRF and KXRF measurements. Ex. 11, Specht 2019 at 8. Dr. Specht explained that "[i]t is likely that these two devices, which use different energies, are sampling different portions of the bone." *Id.* He also observed that there are only "limited" studies of how children absorb and store lead. *Id.* "This," he said, "makes it difficult to assess the abilities of the device in comparison to some standard." *Id*.

Dr. Specht concluded that since pXRF "is a new measurement system, further work needs to be done to determine exactly what biomarker is being measured using pXRF, and how it may relate to the traditional KXRF measurement of bone [lead] and the biokinetics of [lead] in the body." Ex. 11, Specht 2019 at 8; *see id.* at 2 (pXRF "is a new measure of bone [lead], which is still being validated for use in large scale studies"). Thus, at the time Plaintiffs were undergoing pXRF testing in Flint, Dr. Specht elsewhere acknowledged that pXRF testing has not been validated in children and that "further work" is needed to understand this "new measurement system." *Id.* at 8.

2. Recent Studies Of pXRF Testing In Birds And Adults Do Not Demonstrate The Reliability Of pXRF Testing In Children

At his deposition, Dr. Specht insisted that pXRF has been "fully validated" based on two recent papers he published about pXRF testing of bird bones. Dep. 278:5-24 (citing Ex. 12, A. Specht et al., *Feasibility of a Portable X-ray Fluorescence Device for Bone Lead Measurements of Condor Bones*, 615 Sci. of the Total Env't 398 (2018), and Ex. 13, A. Specht et al., *Lead Exposure Biomarkers in the Common Loon*, 647 Sci. of the Total Env't 639 (2019)).

The bird studies do not validate the use of pXRF on children because they do not address the tissue-thickness and bone-composition issues that make pXRF measurements inaccurate in children. The first study, involving condor bones, involved a maximum tissue thickness of 1.54 mm (created using Lucite sheets to mimic tissue). Dep. 374:16-376:8, 382:17-383:5. The second study, involving loon bones, involved a maximum tissue thickness of 3.02 mm. *Id.* at 387:21-389:19. And Dr. Specht does not contend that birds have the same bone composition as children. The studies thus do not solve the tissue-thickness and bone-composition issues that Dr. Specht identified for children.

Dr. Specht also cited a forthcoming paper, set for publication in 2021, reporting on a study of occupationally exposed *adults* ages 38 to 95 in Indiana. *See* Ex. 14, X. Zhang, A. Specht et al., *Evaluation of a Portable XRF Device for In Vivo Quantification of Lead in Bone Among a US population*, 753 Sci. of the Total Env't

no. 142351 (2021) (Zhang 2021). Dr. Specht testified that the study showed "fairly good agreement" between pXRF and KXRF readings. Dep. 408:5-17. But the study, once again, confirms that using pXRF is not appropriate for children. Like the 2014 study, the 2021 study found that pXRF and KXRF readings generally agreed at tissue thicknesses less than 5 mm, but not at tissue thicknesses above 5 mm, where the pXRF test frequently overestimated bone lead levels. Ex. 14, Zhang 2021 at 5 fig.2; *see* Dep. 418:17-419:2 (conceding that "the spread of the data is much larger for the greater than 5 millimeters with a portable XRF"). The study also did not purport to address children's unique bone composition. *See* Ex. 9, Specht 2016 at 6.

Thus, neither the bird studies nor the Indiana study validates pXRF for use in children. The bird studies reveal nothing about the accuracy of pXRF in subjects with thick tissue—because birds do not have thick tissue—and the Indiana study affirmatively shows that pXRF does not work well on subjects with thicker tissue. None of the studies addresses children's unique bone composition.

To this day, there is not a single peer-reviewed study validating the use of pXRF on children, not by Dr. Specht or by anyone else. Dr. Specht asserts that he resolved the issues in using pXRF on children by the time he performed his work in Flint. Dep. 62:15-63:16. But he has never subjected his work in Flint to peer review or otherwise validated the use of pXRF on children. The fact that no testing or peer-

reviewed studies support Dr. Specht's pXRF use on children—and his studies show the opposite—confirms that his methodology is unreliable. *See, e.g.*, *United States v. Smallwood*, No. 5:08-CR-38, 2010 WL 4168823, at *5 (W.D. Ky. Oct. 12, 2010), *aff'd* 456 F. App'x 453 (6th Cir. 2012) (excluding expert testimony because the expert's "own studies appear[ed] to contradict his opinion," his "own research acknowledge[d] that there [was] a lack of reliable data," and "some of [his] own research show[ed] [a contrary conclusion]").

In sum, Dr. Specht's own peer-reviewed and published research and testing shows that pXRF is not reliable for measuring bone lead levels in children. It therefore should not be treated as reliable in this litigation. *See, e.g.*, *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 677 (6th Cir. 2010) ("[W]hat science treats as a useful but untested hypothesis the law should generally treat as inadmissible speculation."). Until pXRF technology has been scientifically validated for use on children, it should not be admitted in the courtroom.

3. Dr. Specht's pXRF Measurements Cannot Be Replicated

Dr. Specht's pXRF methodology is unreliable for an additional reason. The "primary requirement" under *Daubert*'s "testability factor" "is that '[s]omeone else using the same data and methods . . . be able to replicate the result[s].'" *City of Pomona v. SQM N. Am. Corp.*, 750 F.3d 1036, 1047 (9th Cir. 2014) (quoting *Zenith Elecs. Corp. v. WH-TV Broad. Corp.*, 395 F.3d 416, 419 (7th Cir. 2005)).

No one can replicate the pXRF bone lead measurements that nurses working for Plaintiffs' counsel took under Dr. Specht's oversight. The pXRF devices that they used had been specially modified by Dr. Specht and included specially modified software to which Dr. Specht concedes "[n]o one else" in the world has access. Dep. 499:13-21. Indeed, besides himself and his colleagues, Dr. Specht is not aware of anyone else in the world who is using pXRF devices (let alone his jury-rigged devices) to measure bone lead. *Id.* at 307:2-20.[4]

The inability to replicate Dr. Specht's pXRF testing was recently confirmed when the *Washington* and *Chapman* plaintiffs attempted to set up their own bone lead testing facility in Flint. They retained two doctors—Dr. Andrew Christian Todd, a physicist at the Icahn School of Medicine at Mount Sinai who has studied bone lead since the 1980s, and Dr. Karl John Jepsen, a Professor at the School of Medicine at the University of Michigan—and attempted to work with Dr. Specht and the pXRF device manufacturer to replicate his pXRF testing. *See* Washington & Chapman Pls.' Mot. to Extend Deadlines, *In re Flint Water Litig.*, No. 16-cv-10444 ECF No. 1494, PageID.58109-58126; Aff. of Andrew Christian Todd, Ph.D.

[4] It is not clear even that Dr. Specht can replicate his own team's measurements of Plaintiffs. The nurses hired by Plaintiffs' counsel took only one reading of each Plaintiff and made no attempt to verify that the pXRF devices produced consistent results (such as by taking a second reading as a control check). Report 7-20.

& Karl John Jepsen, Ph.D., *Flint Water Litig.*, No. 16-cv-10444 ECF No. 1497, PageID.58184-58187 (Todd & Jepsen Aff.).

Dr. Todd and Dr. Jepsen were unable to replicate Dr. Specht's pXRF testing because he did not share his protocols (including details of his calibration methods and process), despite committing to do so, and because the device manufacturer "specifically stated [that it] would not sell the XRF device as modified for use by Dr. Specht" and "would not provide confirmation that the device was acceptable to use for in vivo testing." Todd & Jepsen Aff. 2-3, No. 16-cv-10444 ECF No. 1497, PageID.58185-58186. Dr. Todd and Dr. Jepsen therefore concluded that their "attempt to establish a second bone lead assessment site has failed," and noted that "[t]he fact that the manufacturer is unwilling to stand behind the use of this device on humans would put undue liability on the part of us and our employers, and would potentially expose us to reputational damage which we are unwilling to accept." *Id.* at 4, PageID.58187. The fact that Dr. Specht's testing results cannot be replicated underscores that his pXRF methodology is not reliable.

B. pXRF Has Significant Error Rates, And There Are No Standards Controlling Its Operation

In evaluating the admissibility of a particular scientific technique, courts also consider "the known or potential rate of error . . . and the existence and maintenance of standards controlling the technique's operation." *Daubert*, 509 U.S. at 594

(internal citation omitted). These factors also cut against using pXRF to measure bone lead in children.

Dr. Specht's own research found that the use of pXRF on children has too high of an error rate to be reliable at this point. *See* Ex. 9, Specht 2016 at 7 (concluding that pXRF "has limitations for bone [lead] measurements in children based on calibration, which need to be addressed before being used further in pediatric populations"); Ex. 11, Specht 2019 at 8 (concluding that "[s]ince [pXRF] is a new measurement system, further work needs to be done to determine exactly what biomarker is being measured using the pXRF, and how it may relate to the traditional KXRF measurement of bone [lead]").

Further, no established standards exist to control the use of Dr. Specht's handheld pXRF devices to measure bone lead (let alone in children). With each research paper, Dr. Specht has continued to adjust the calibration and measurement time of his pXRF device. For example, after performing three-minute measurements in Flint, Dr. Specht increased the measurement time in his Indiana study to five minutes for some study participants "[t]o further improve the sensitivity of the portable XRF" and "reduce[] the measurement uncertainty." Ex. 14, Zhang 2021 at 6. Even Dr. Specht has yet to settle on a standard methodology. That fact weighs heavily against the conclusion that pXRF is a reliable methodology for measuring bone lead levels.

C. pXRF Is Not Generally Accepted For Measuring Bone Lead In Children

Another factor in assessing the reliability of expert testimony under *Daubert* is "whether the theory or technique has been generally accepted in the particular scientific field." *United States v. Semrau*, 693 F.3d 510, 520 (6th Cir. 2012) (quoting *United States v. Bonds*, 12 F.3d 540, 558 (6th Cir. 1993)). "Widespread acceptance can be an important factor in ruling particular evidence admissible, and 'a known technique which has been able to attract only minimal support within the community' may properly be viewed with skepticism." *Daubert*, 509 U.S. at 594 (internal citation omitted).

Dr. Specht's use of a handheld pXRF device to measure bone lead in children should be viewed with great skepticism. Not a single scientific paper has validated the use of pXRF for that purpose. Since at least 2011, Dr. Specht and his colleagues have attempted to validate the accuracy of their pXRF device by comparing it to what Dr. Specht describes as the "gold standard" KXRF. But they have never succeeded in validating their pXRF device to measure bone lead in children. As recently as 2019, Dr. Specht acknowledged, in a peer-reviewed paper, that pXRF technology has *not* been validated as accurately measuring bone lead in children due to the confounding effects of children's soft tissue thickness and bone composition. *See* pp. 12-16, *supra*.

Moreover, Dr. Specht is not aware of anyone besides himself and his colleagues at Purdue and Harvard who is even attempting to use pXRF to measure bone lead in anyone, let alone children. Dep. 307:2-20. And even Dr. Specht and his colleagues have never received approval to perform research using pXRF devices on children in the United States; the only studies they have performed on children to date have been in China. *See* pp. 12-16, *supra*. The fact that no other scientists are employing this pXRF methodology, and that Dr. Specht and his colleagues have never received approval to use pXRF on children in the United States even for research purposes, shows that it is not generally accepted. *See, e.g.*, *Allgood v. Gen. Motors Corp.*, No. 102CV1077DFHTAB, 2006 WL 2669337, at *17 (S.D. Ind. Sept. 18, 2006) (excluding expert's methodology for fingerprinting PCBs because he "did not know of any other scientist" who had used the methodology and "could not cite any published literature or [regulatory] guidance supporting" the methodology).

One of Dr. Specht's coauthors for his 2016 study in China, Dr. Hu, agrees that pXRF is not an accepted way to measure bone lead in children. *See* Ex. 6, Finley Report 91-92 (recounting Dr. Hu's testimony). Dr. Hu, who has been retained by the class plaintiffs, has studied bone lead since the 1980s and has published 80 to 100 papers on the topic. Ex. 15, Hu Dep. 382:1-6. Dr. Hu explained that he did not perform bone lead testing in Flint because he "[didn't] really see its utility." *Id.* at 382:7-13. He explained that, among other limitations, bone lead measurements in

children have "more measurement error" and are "less precise." *Id.* at 382:14-383:6. And with respect to pXRF in particular, Dr. Hu testified that, although it has been used in research settings, "other than that, I'm not aware of it being widely used for other purposes." *Id.* at 384:10-22. Dr. Hu explained that pXRF has not been used to diagnose a particular child or anyone else as having been exposed to elevated levels of lead or being at risk of any lead-related health effects. *Id.*

Several prominent Flint pediatricians have also voiced significant concerns about Dr. Specht's pXRF testing, further demonstrating its lack of general acceptance. Dr. Mona Hanna-Attisha was one of the first people to raise concerns over lead exposure from the Flint water crisis. She recently spoke out against the use of pXRF devices on children in Flint, stating that "[f]or so long, the people of Flint have felt, you know, experimented on, and rightly so, and this is another example of this injustice—where something is being applied on them that is not tested, that has not been approved." Ron Forger, *Flint Pediatrician Who Blew the Whistle on Water Crisis Won't Recommend Bone Scans for Kids*, Mlive (Mar. 15, 2021), https://bit.ly/3nJkLk8. She further explained that "[b]one scans are never a good idea for children" and that "[h]owever minimal the risk [from radiation] there is no benefit" because bone scans provide no information about where the lead came from or when. *Id.*

Dr. Lawrence Reynolds has voiced similar concerns. *See* Objections of Dr. Lawrence A. Reynolds, M.D., FAAP Regarding the Proposed Flint Water Settlement Agreement, *Flint Water Litig.*, No. 16-cv-10444 ECF No. 1436, PageID.55021-55050. Dr. Reynolds has been a pediatrician in Flint for many decades and served on the Flint Water Advisory Task Force. *Id.* at 2-3, PageID.55022-55023. Dr. Reynolds stated that "[u]se of this unapproved industrial device to perform a bone scan on live humans . . . is at best[] unauthorized research." *Id*. at 6, PageID.55026. He noted that it is not "part of an approved diagnostic procedure" or "a proven beneficial treatment protocol, especially for children," and it is "not an approved practice by any global regulatory agency or professional body." *Id.* In fact, he explained, the "XRF hand held device is not designed to be used on human beings—at all." *Id.* Dr. Reynolds concluded that Dr. Specht's pXRF testing is an "unauthorized/unsupervised research project" "masquerading as an accepted medical procedure." *Id.* at 9, PageID.55029. He even went so far as to call Dr. Specht's pXRF testing "a human rights violation . . . the Tuskegee experiment all over again." Ron Forger, *Flint Mayor's Health Advisor Calls Water Settlement Bone Lead Testing "A Human Rights Violation,"* Mlive (Mar. 1, 2021), https://bit.ly/3xEZMTW.

In response to criticism from Dr. Reynolds and others, Plaintiffs' counsel argued that Dr. Specht's pXRF devices do not need FDA approval because the

devices are being used for litigation purposes, and not for "diagnosis, prevention, or treatment of any disease." Ltr. from C. Stern & H. Shkolnik 4, *In re Flint Water Litig.*, No. 16-cv-10444 ECF No. 1455, PageID.57130. But even if Plaintiffs were correct, that position only underscores pXRF's lack of general acceptance. A methodology that lacks general acceptance, or even basic regulatory approval, for actual medical use outside the courtroom is not a reliable methodology inside the courtroom. *See, e.g.*, *Kumho Tire*, 526 U.S. at 152 (explaining that *Daubert*'s objective "is to make certain that an expert … employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field"); *Newell Rubbermaid, Inc. v. Raymond Corp.*, 676 F.3d 521, 527 (6th Cir. 2012) ("if a purported expert's opinion was prepared solely for litigation, that may also be considered as a basis for exclusion").

The lack of general acceptance of pXRF to measure bone lead in anyone—let alone children—strongly cuts against its reliability.

II. Dr. Specht's Opinions Regarding The Significance Of Plaintiffs' Bone Lead Measurements Are Unreliable

Based on the pXRF bone lead readings taken under his direction, Dr. Specht opines that Plaintiffs experienced [redacted] which he defines further as a [redacted] Report 13-14, 16-17, 19-20. He compares Plaintiffs' bone lead levels to those of children

studied in China and Canada, suggesting that these comparisons demonstrate [redacted]. *Id.* at 7.

Dr. Specht's opinions rest on speculation, not science. There are no established benchmarks for [redacted] bone lead (let alone for measurements taken using pXRF); the China and Canada studies do not support Dr. Specht's conclusions; and Dr. Specht did not even try to test a control group. Dr. Specht's conclusion that his measurements reveal [redacted] lacks a reliable foundation. The measurements themselves also should be excluded, because without reliable testimony about their significance, the readings cannot help the trier of fact resolve any issue in the case.

A. There Is No Established Standard For Quantifying [redacted] Bone Lead Levels

According to the measurements taken using Dr. Specht's pXRF devices, Plaintiffs had bone lead levels of [redacted] Report 7-20. But Dr. Specht did not—and could not—identify any baseline against which to compare those numbers. There are no regulatory reference values for bone lead. There also is no scientific consensus as to what would constitute [redacted] bone lead. Because there are no established benchmarks with which to compare Plaintiffs' bone lead measurements, Dr. Specht's opinions that Plaintiffs' bone lead levels demonstrate [redacted] are unreliable and should be excluded.

Dr. Specht admits that there are no reliable benchmarks. In his 2016 study of children in China, Dr. Specht acknowledged that, although KXRF technology had been around for decades, "not many studies have been performed on children using a bone [lead] biomarker" and "[t]here is a significant gap in understanding . . . the usefulness of bone [lead] as a biomarker for [lead] exposure and toxicity among children." Ex. 9, Specht 2016 at 2. And in his 2019 follow-up study, Dr. Specht similarly acknowledged that, "since the subjects of this study were children, this issue is complicated further as studies of [lead] biokinetics and storage in children are limited. This makes it difficult to assess the abilities of the device in comparison to some standard." Ex. 11, Specht 2019 at 8. Dr. Specht admits that "[t]o [his] knowledge, there has been no scientific conclusion as to what the usual bone lead would be versus a high bone lead." Dep. 333:24-334:10.

Dr. Hu made the same concession, albeit in a more pointed way. When asked how he would identify [redacted] bone lead, Dr. Hu answered: "[redacted] compared to what? That would be my response." Ex. 15, Hu Dep. 385:8-14. He explained that "[t]here are no standards for bone lead levels in either children or adults." *Id.* at 386:1-7.

Dr. Specht also admitted that there are no publicly available bone lead data on children in the United States. Dep. 334:11-335:10. That starkly differentiates bone lead levels from blood lead levels, which have been closely tracked in the United

States for decades. Thus, Dr. Specht's testimony that Plaintiffs' bone lead levels reflect a [redacted] to lead, Report 14, 16-17, 19, is nothing more than his own say-so. To be admissible, an opinion must be supported by more than "the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). In the absence of any established reference values for bone lead in children, Dr. Specht's opinion that Plaintiffs experienced [redacted] to lead during development is "simply a hypothesis presented in the guise of knowledge." *Valentine v. Jones Lang LaSalle Ams., Inc.*, No. 13-cv-10888, 2014 WL 4906726, at *4 (E.D. Mich. Sept. 30, 2014) (Levy, J.).

In an apparent attempt to provide some point of comparison, Dr. Specht's bone lead report for each bellwether plaintiff provides "Reference Values," stating that a bone lead level above [redacted] and a level above [redacted] *E.g.*, Ex. 16, Bone Lead Report (E.S.). In his deposition, Dr. Specht cited unspecified literature involving adults as the basis for these "Reference Values"—but he ultimately conceded that the literature "wouldn't be relevant" to children. Dep. 432:1-436:3. He further conceded that he has not attempted to identify any similar "Reference Values" for children. *Id.* at 436:15-23. In any event, [redacted], so the "Reference Values" identified by Dr. Specht in his report serve only to undermine his opinions.

Without any standard for what constitutes an [redacted] bone lead level, Dr. Specht asserts that *any* bone lead level higher than the uncertainty value generated by his pXRF device for that measurement is proof of [redacted]. *E.g.*, Report 7-8. But measurement uncertainty merely reflects the accuracy of the measurement. It is not a baseline. Dep. 268:1-3 ("uncertainty" simply represents the degree, "plus or minus," to which Plaintiffs' actual bone lead level may differ from the measurement).[5] Whether the uncertainty value for a particular measurement is less than the measurement says nothing about whether Plaintiffs' bone lead levels are (or are not) [redacted]. The fact that the uncertainty value is less than the measurement means only that the real bone lead level is [redacted] (assuming Dr. Specht's pXRF devices are accurately calculating bone lead levels and uncertainty values). It says nothing about whether the real bone lead level [redacted]. When pressed, Dr. Specht admitted that the most he could infer was that Plaintiffs' bone lead levels [redacted]. *Id.* at 140:5-8.

5 [redacted]

B. The China And Canada Studies Do Not Support Dr. Specht's Opinions

Dr. Specht attempts to rely on "[r]eference studies" completed "in a few comparable groups" in China and Canada. Report 6-7. He compares the Flint bone lead measurements to data from those studies, asserting that, based on these comparisons, Plaintiffs' bone lead levels reflect [redacted]. *Id.* Dr. Specht's inferences from the China and Canada studies are not reliable because "there is simply too great an analytical gap between the data and the opinion proffered." *Joiner*, 522 U.S. at 146-47.

1. Dr. Specht's Comparisons To The China Studies Are Invalid

Citing his China studies, Dr. Specht contends that Plaintiffs' bone lead levels [redacted] Report 7. [redacted]. The China studies reported mean bone lead levels in exposed children of 28.23 µg/g using pXRF and 20.91 µg/g using KXRF, and mean bone lead levels in the unexposed control group of 3.8 µg/g using pXRF and -0.93 µg/g using KXRF. *See* Ex. 11, Specht 2019 at 19 tbl.2.[6] [redacted]

[6] Dr. Specht explained that the negative KXRF readings in the unexposed control group were due to measurement uncertainty. Dep. 267:16-268:7.

[redacted] *Id.* at 7-20.

In his deposition, Dr. Specht attempted to reconcile his opinions with the China study results—without success. First, Dr. Specht explained that his opinion is based on a comparison between the *pXRF* readings in Flint and the *KXRF* readings in China. Dep. 457:5-13. The mean of the KXRF measurements in the control group in China was -0.93 µg/g—essentially zero. Ex. 11, Specht 2019 at 19 tbl.2. Based on that, Dr. Specht contends that *any* pXRF reading in Flint above zero is more consistent with the exposed group in China than with the control group. Dep. 461:16-462:8.

Dr. Specht's apples-to-oranges comparison does not hold up. His own papers make clear that mixing and matching pXRF and KXRF readings is not reliable, particularly in children. As Dr. Specht wrote in his 2019 China paper, "[i]t is likely that these two devices, which use different energies, are sampling different portions of the bone," and "further work needs to be done to determine exactly what biomarker is being measured using the pXRF, and how it may relate to the traditional KXRF measurement of bone [lead]." Ex. 11, Specht 2019 at 8. His 2014 study makes the same point. *See* Ex. 7, Specht 2014 at 6 ("[W]ith the low penetration

depth of the LXRF [in the pXRF device], the KXRF and the portable XRF systems are sampling different sites of the bone. KXRF would be sampling the whole bone and LXRF would be sampling the superficial 0.5-1 mm of the bone. It is not very clear how [lead] distributes over the layer of tibia bone and the literature on this topic is limited."). Dr. Specht's attempt to compare pXRF readings in Flint to KXRF readings in China is therefore not reliable according to his own published, peer-reviewed research. *See, e.g.*, *State Farm Fire & Cas. Co. v. Electrolux Home Prods., Inc.*, 980 F. Supp. 2d 1031, 1049-50 (N.D. Ind. 2013) (explaining that "'care must be taken to be sure that the comparison is one between 'apples and apples,'" and finding that "using . . . two different types of data amounts to a comparison between 'apples and oranges,' which fails to meet *Daubert*'s reliability standard").

Second, Dr. Specht contends that the three-minute pXRF readings taken in Flint (which showed a mean of [redacted]) should not be compared to the two-minute pXRF readings taken in China (which showed a mean in the unexposed group of 3.8 µg/g) due to the different measurement times. Dep. 181:3-16, 258:21-259:4, 300:4-301:18. But the same reasoning precludes Dr. Specht's attempt to compare the three-minute *pXRF* readings taken in Flint to the 30-minute *KXRF* readings taken in China. Not only are the measurement times vastly different, but Dr. Specht's own papers show that pXRF readings in children (or in adults with thicker tissue) are not comparable to KXRF readings.

Third, Dr. Specht attempts to close the substantial gap between the bone lead levels of exposed children in his China study and the bone lead levels measured in Flint by asserting that the *median* (middle value) bone lead levels of the exposed children in his China study should be considered instead of the substantially higher *mean* (average) bone lead levels. Although Dr. Specht reported mean bone lead levels in his published, peer-reviewed research (which were 28.23 µg/g using pXRF and 20.91 µg/g using KXRF), for purposes of this litigation he went back to his raw data from China and calculated a median bone lead level in the exposed group of 12 µg/g using KXRF measurements. Report 6. He now claims that the median is a "better reflection" of the bone lead levels of exposed children in the China study because he thinks that the mean is "heavily skewed." Dep. 438:17-439:4. But Dr. Specht does not explain why he chose to publish the mean rather than the median if the median is the more reliable number.

Dr. Specht's decision to set aside the data he published, in favor of numbers tailored for litigation, shows that his methodology is not reliable. *See, e.g.*, *Kumho Tire*, 526 U.S. at 152 (experts must "employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field"). And even if the median of the 30-minute KXRF measurements in China were considered a relevant figure, it would not support Dr. Specht's opinion [redacted]

[redacted] More broadly, Dr. Specht has not shown that the median bone lead level among the 3,000 plaintiffs measured in Flint is anywhere close to 12 µg/g.

2. The Canada Study Does Not Support Dr. Specht's Conclusions

Dr. Specht also cites a study performed on children in Ontario, Canada. Report at 6-7 (citing Ex. 17, F. McNeill et al., *The Decrease in Population Bone Lead Levels in Canada Between 1993 and 2010 as Assessed by In Vivo XRF*, 39 Physiological Measurement no. 015005 (2018) (McNeill 2018)). Using KXRF, the study reported a mean bone lead level of 0.63 µg/g. *Id.* at 6. Dr. Specht opines that the bone lead results in Flint were "6.8 times higher on average than children in Ontario," *id.* at 7, which would equate to an average in Flint of 4.28 µg/g.[7]

Dr. Specht's comparisons to children in Canada are not reliable. First, the Canadian study measured bone lead using KXRF technology. Dep. 474:16-475:3. Dr. Specht is once again comparing apples to oranges by comparing pXRF readings in Flint to KXRF readings in Canada. His own research showed that pXRF and KXRF readings in children are not comparable. *See* pp. 12-16, *supra*. For example, in his China study, bone lead levels measured in the same unexposed children were

[7] Dr. Specht's report does not explain how he calculated his "6.8 times higher" number. In his deposition, he said that he calculated the average based on however many of the 3,000 Flint plaintiffs had "testing . . . done by that time" but stated that he "do[es] not believe [that he has] that information anymore." Dep. 467:19-469:23.

at least 3.8 µg/g higher using pXRF (3.8 µg/g) compared to KXRF (negative 0.93 µg/g or essentially zero). Ex. 11, Specht 2019 at 19 tbl.2. Notably, the difference of at least 3.8 µg/g between the pXRF and KXRF measurements in his own research among children with no discernible lead exposure exceeds the 3.65 µg/g difference between the pXRF readings in Flint and the KXRF readings in Canada.

Dr. Specht treats that 3.65 µg/g difference as proof that children in Flint were exposed to more lead than children in Canada. Report 15, 17-18, 20. But his China study shows that the difference instead is likely explained by the different measurement methodology. Because Dr. Specht can identify no evidence to support attributing the difference to lead exposure, his opinions are unreliable and should be excluded. *See, e.g.*, *Mohney v. USA Hockey, Inc.*, 138 F. App'x 804, 809 (6th Cir. 2005) (affirming exclusion of testimony of expert who used "estimates and assumptions" rather than "the actual data" in reaching his opinion); *Kalamazoo River Study Grp. v. Rockwell Int'l Corp.*, 171 F.3d 1065, 1072 (6th Cir. 1999) (affirming exclusion of testimony of expert whose "conclusion was based on 'speculation, conjecture, and possibility'" as opposed to a "'factual basis'").

Second, Dr. Specht cannot establish that the children studied in the Canada paper are comparable to children in Flint. The Canadian paper studied 50 children drawn from "a mixed ethnic and socio-economic population" in and around Toronto. Ex. 17, McNeill 2018 at 2-3. Flint children would be expected to have more

background exposure to lead (apart from any issues related to the change in water source) as a result of Flint's industrial history and the prevalence of lead-based paint in Flint's older homes. *See* Ex. 6, Finley Report 6-16. Accordingly, any difference between the bone lead levels observed in Flint and those observed in the Canada study may result from differences in background exposure experienced broadly by the Flint population, and does not show that a particular child suffered an episode of heightened lead exposure from a particular source.

C. Dr. Specht Failed To Perform Any Control-Group Testing

To make a reliable comparison, Dr. Specht needed to test a control group—a group of children in or around Flint who were not exposed to lead as a result of the Flint water crisis. *See, e.g.*, *Pick v. Am. Med. Sys., Inc.*, 958 F. Supp. 1151, 1161 (E.D. La. 1997) ("[C]ourts have frequently rejected case studies as an insufficient basis to decide causation when they lack control groups.") (collecting cases); *Weaver v. Champion Petfoods USA Inc.*, No. 18-CV-1996-JPS-JPS, 2019 WL 7370374, at *5 (E.D. Wis. Dec. 31, 2019) (excluding survey results because the survey "lack[ed] . . . a meaningful control group"); *Bushore v. Dow Corning-Wright Corp.*, No. 92-344-CIV-T-26C, 1999 WL 1116920, at *5 (M.D. Fla. Nov. 15, 1999) (explaining that "'assessing the strength of association requires studies with appropriate control groups'").

Dr. Specht did not test a control group. He testified that he "was tasked to just measure the bone lead content of the community, and these Bellwether clients specifically." Dep. 338:10-17. By forgoing the use of a control group, Dr. Specht departed from his own past practice outside of litigation. In his China studies, for example, Dr. Specht tested bone lead levels in both lead-poisoned children and an unexposed control group in a nearby town. Ex. 9, Specht 2016 at 2; Ex. 11, Specht 2019 at 2. Dr. Specht's failure to test a control group renders unreliable his opinion that Plaintiffs' bone lead levels reflect a [redacted] Report 14, 16-17, 19. He simply did not attempt to establish any "baseline."

D. The Lack Of Any Relevant Baseline Or Control Group Data Renders Dr. Specht's Opinions Inadmissible

Because Dr. Specht can cite no established benchmarks or reliable control group data, his opinion that Plaintiffs' bone lead measurements reveal [redacted] amounts to nothing "more than subjective belief and unsupported speculation." *McLean v. 988011 Ont., Ltd.*, 224 F.3d 797, 800-01 (6th Cir. 2000) (quoting *Pomella v. Regency Coach Lines, Ltd.*, 899 F. Supp. 335, 342 (E.D. Mich. 1995)). And because Dr. Specht cannot reliably opine on what the bone lead levels mean, the measurements themselves cannot assist the jury to resolve any issue in the case, so the measurements also should be excluded as irrelevant and unhelpful.

For similar reasons, another district court excluded expert testimony regarding KXRF measurements of bone lead. *See Dombrowski v Gould Elecs., Inc*, 31 F.

Supp. 2d 436, 442 (M.D. Pa. 1998). The plaintiffs in *Dombrowski* sought to use KXRF bone lead measurements as part of a medical-monitoring program to identify residents living near an industrial facility who were exposed to elevated levels of lead. In addition to concerns about the general reliability of KXRF technology, the court explained, "there is no agreed upon standard against which to test the readings, even if one were to agree that the proposed . . . equipment was acknowledged to be capable of acceptable readings." *Id.* The court explained that the lack of any baseline made it "impossible to decide the significance of what the readings might happen to be." *Id.* Accordingly, the court excluded the expert testimony on the availability of this monitoring procedure. *Id.*

This Court should do the same. There is no standard against which to compare Dr. Specht's pXRF readings, and Dr. Specht's pXRF methodology is even more unreliable than the KXRF methodology at issue in *Dombrowski*.

III. Because Dr. Specht Cannot Trace Bone Lead To Particular Sources, His Opinions Would Not Be Helpful To A Jury And Would Be Substantially More Prejudicial Than Probative

Dr. Specht's bone lead readings and his opinions about their meaning should be excluded for another reason. Because Dr. Specht cannot trace lead in Plaintiffs' bones to any particular source, all the measurements can show is that Plaintiffs were exposed to lead at some point in their lives. They cannot show that Plaintiffs were exposed to additional lead as a result of the Flint water crisis in general, let alone

because of VNA in particular. The results and Dr. Specht's related opinions thus are not relevant to a fact in dispute. They will not "help the trier of fact to understand the evidence or to determine a fact in issue," Fed. R. Evid. 702(a), and they have no "tendency to make a fact more or less probable," Fed. R. Evid. 401(a), 402, so they should be excluded. Further, if presented to the jury, the results and related opinions would be "confusing" and "misleading" and substantially more prejudicial than probative, so they should be excluded under Federal Rule of Evidence 403.

Dr. Specht concedes that lead measured in bone "is reflective of years to decades worth of exposure." Report 4. He admits that bone lead is a tool for "determining *cumulative* exposure to lead over years to decades." *Id.* at 3 (emphasis added). At his deposition, Dr. Specht confirmed that he is not offering opinions as to "how the lead got into the children's body" and is "only [] offering [] testimony in regards to what the lead levels were from the bone." Dep. 210:2-11. Dr. Hu agreed that identifying the source of lead measured in bone is not "something that can be done." Ex. 15, Hu Dep. 386:8-11.

Dr. Specht's inability to trace bone lead to particular sources is especially significant here because Plaintiffs' toxicologist, Joseph Graziano, Ph.D., conceded that all children in America have some lead in their bodies, and that all children in Flint were exposed to lead before the City of Flint changed its water source in 2014. Ex. 18, Graziano Dep. 68:12-69:13. Indeed, one of the four Plaintiffs in the first

trial group had a [redacted] *before* the switch to Flint River water. [redacted] That lead could come from a variety of sources, including lead paint and baby food. *See, e.g.*, H. Comm. on Oversight & Reform, Subcomm. on Econ. and Consumer Pol'y, *Baby Foods Are Tainted with Dangerous Levels of Arsenic, Lead, Cadmium, and Mercury* (Feb. 4, 2021); Ex. 6, Finley Report 6, 13.

In fact, it is well documented that Flint children experienced *larger* lead exposures before the 2014-2015 water crisis. For example, mean blood lead levels were consistently higher in Flint throughout the early 2010s (peaking at 1.87 ug/dL in 2011) than they were in 2014-2015 (1.19 and 1.30 ug/dL, respectively). *See* Ex. 20, H. Gomez et al., *Blood Lead Levels of Children in Flint, Michigan: 2006-2016*, 197 J. of Pediatrics 158, 161 fig.2 (2018). Mean blood lead levels were also higher in the same 18-month time period in 2012-2013 (1.47 ug/dL), compared to the 18-month period in 2014-2015 when the City of Flint was using the Flint River as its water source (1.32 ug/dL). *See* Ex. 21, H. Gomez et al., *Analysis of Blood Lead Levels of Young Children in Flint, Michigan Before and During the 18-Month Switch to Flint River Water*, 57 Clinical Toxicology 790, 792 fig.1 (2019).

[8] The other three Plaintiffs who have been selected for the first trial were not tested for blood lead before the switch to Flint River water.

A recent analysis of sewage sludge in Flint also concluded that water lead levels spiked significantly in 2011—far more than they did after the switch to Flint River water in 2014. *See* Ex. 22, S. Roy et al., *Efficacy of Corrosion Control and Pipe Replacement in Reducing Citywide Lead Exposure During the Flint, MI Water System Recovery*, 6 Env't Sci.: Water Rsch. & Tech. 3024, at 4 fig.1 (2020). Moreover, that same analysis showed that, after increasing following the water switch, water lead levels returned to pre-switch levels by late summer 2014, long before VNA began working for Flint. *Id.* Therefore, Plaintiffs' bone lead levels—even if Plaintiffs could prove that they were [redacted] due to lead in drinking water—may be the result of previous water lead level spikes that predate VNA's engagement in Flint.

The mere fact that Plaintiffs' bones contain lead, therefore, does nothing to establish that the Flint water crisis (much less any alleged act or omission by VNA) caused them to have additional lead in their bones. Because Dr. Specht cannot trace Plaintiffs' bone lead levels to the Flint water crisis, let alone to VNA, his opinions do not show "a connection between the scientific research or test result being offered and . . . disputed factual issues in the case." *Pride*, 218 F.3d at 578. Those opinions therefore would not be helpful to the jury and should be excluded under Rules 702 and 402.

Dr. Specht's opinions also should be excluded under Rule 403, because any marginal probative value they may have would be substantially outweighed by the risks of jury confusion and prejudice. It is undisputed that Plaintiffs' bone lead levels reflect cumulative exposure to a ubiquitous substance. The lead cannot be traced to drinking water, to the Flint water crisis in particular, or to any alleged negligence on VNA's part. If the bone lead levels are introduced, however, the very idea that Plaintiffs have lead in their bodies may prejudice the jury against VNA. The jury may become confused into believing that the water crisis—and VNA's alleged acts and omissions in particular—*caused* the levels of lead in Plaintiffs' bones. *See Turner v. Allstate Ins. Co.*, 902 F.2d 1208, 1214 (6th Cir. 1990) (affirming exclusion of statistical data under Rule 403 based on trial court's judgment that "the jury may well have been confused by them and may have assigned an inappropriately high [degree] of reliability to them"). Whatever negligible probative value Dr. Specht's testimony may have does not outweigh that risk.

IV. Dr. Specht's Opinion About The Half Life Of Blood Lead Is Unreliable

Dr. Specht focuses on bone lead because, in his view, the ability of blood lead to serve "as a biomarker of exposure [is] severely lacking." Report 3. He opines that "[p]revious studies" have shown that the half-life of lead in children's blood is "less than one week," which he concludes makes blood lead measurements

"incredibly time sensitive." *Id.* Plaintiffs seek to use Dr. Specht's "less than one week" half-life opinion to explain away their [redacted].

Dr. Specht bases his half-life opinion on his own, limited research on the issue, and even then embellishes his own findings. The "[p]revious studies" cited by Dr. Specht are two of his own papers from his China bone lead work during which some blood lead measurements were also taken. Report 3. In the first paper, he estimated a blood lead half-life of *9.96 days* (plus or minus 3.92 days) based on a sample size of 13 children. *See* Ex. 9, Specht 2016 at 1, 6, 14. In the second paper, he estimated a blood lead half-life of *19.3 days* (plus or minus 14.1 days) for children over the age of three, based on a sample size of 33 children, and *6.9 days* (plus or minus 4.0 days) for children aged one to three, based on a sample size of 17 children. *See* Ex. 11, Specht 2019 at 1, 21. Dr. Specht therefore embellishes even his own, limited research, which shows that his opinion is not reliable. *See, e.g.*, *Adams v. Cooper Indus., Inc.*, No. 03-476-JBC, 2007 WL 1805586, at *5-7 (E.D. Ky. June 21, 2007) (excluding testimony because expert "exaggerated," misstated, and selectively "ignore[d]" aspects of the studies he used to reach his conclusion).

Moreover, if Dr. Specht had reviewed the broader scientific literature on blood lead half-lives in children, he would have seen that the half-life of lead in children's blood actually is quite long—typically a year or more. VNA's expert toxicologist Dr. Brent Finley explains in his report that "there are many published estimates of

the time required for blood lead levels to decline in lead-exposed children, and these values are far longer than the value calculated by Dr. Specht." Ex. 6, Finley Report 81. Dr. Finley highlights three studies in particular:

- In a 2000 study of 42 children, the authors determined that the blood lead half-life for acutely exposed children was 8 to 11 months, while the blood lead half-life for chronically exposed children was 20 to 38 months. Ex. 6, Finley Report 81.
- In a 2001 study of 579 children, the authors determined that, on average, blood lead levels of 25-29 µg/dL decreased to 10 µg/dL in 24.0 months, blood lead levels of 20-24 µg/dL decreased to 10 µg/dL in 20.9 months, blood lead levels of 15-19 µg/dL decreased to 10 µg/dL in 14.3 months, and blood lead levels of 10-14 µg/dL decreased to 10 µg/dL in 9.2 months. Ex. 6, Finley Report 81.
- In a 2008 study of 996 children with an average blood lead level of 19.6 µg/dL, it took approximately 382 days on average for a child's blood lead to decrease to 10 µg/dL. Ex. 6, Finley Report 81.

Dr. Specht made no effort in his report to address the broader scientific literature on blood lead half-lives in children. Instead, he ignores those studies entirely and asserts unequivocally that "[p]revious studies" have shown that children have a blood lead half-life of "less than one week." Report 3. An expert opinion

that rests on cherry-picked studies (his own studies, which he distorts) and fails to address contrary studies is not reliable.[9] *See, e.g.*, *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 634 (4th Cir. 2018) ("Result-driven analysis, or cherry-picking, undermines principles of the scientific method and is a quintessential example of applying methodologies . . . in an unreliable fashion."); *see also In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 799-800 (3d Cir. 2017); *Milward v. Rust-Oleum Corp.*, 820 F.3d 469, 475 (1st Cir. 2016); *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 883-84 (10th Cir. 2005); *Barber v. United Airlines, Inc.*, 17 F. App'x 433, 437 (7th Cir. 2001); *In re Incretin-Based Therapies Prods. Liab. Litig.*, —F. Supp. 3d—, No. 13-md-2452, 2021 WL 880316, at *21 (S.D. Cal. Mar. 9, 2021).

Accordingly, Dr. Specht's opinion about the half-life of lead in blood is unreliable and should be excluded.

[9] Moreover, as someone who has spent his career trying (unsuccessfully) to validate a novel technology for measuring exposure to lead in children, Dr. Specht has a vested interest in undermining the usefulness of blood-lead testing. That makes his exclusive reliance on his own results—which are notably different from the otherwise consistent results reached by independent researchers—particularly problematic.

CONCLUSION

The Court should exclude the testimony and report of Dr. Aaron Specht.

Respectfully submitted,

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Dated: May 11, 2021

CERTIFICATE OF SERVICE

I hereby certify that on May 11, 2021, I electronically filed the foregoing document with the Clerk of the Court using the ECF System, which will send notification to the ECF counsel of record.

Respectfully submitted,

/s/ James M. Campbell

Dated: May 11, 2021